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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,731	10/23/2003	Cornelia Berghof	930008-2023.1	8400

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,731	BERGHOF ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claim 22 and newly added claims 29-32 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied, as necessitated by amendment, or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejections under 35 USC 102(b) made in the previous office action are withdrawn in view of the amendments to the claims. Claim 22 has been amended to be drawn to at least 5 isolated nucleic acid molecules which are selected from the group consisting of SEQ ID NO 6, 7, 8, 9, 10, and the complement of SEQ ID NOS 6, 7, 8, 9, 10. As recited, the claims limit the set to at least 5 molecules where each is one of SEQ ID NOS 6-10 or the complement of SEQ ID NO 6-10. Accordingly, a set where all molecules comprise the indicated SEQ ID NOS along with additional sequences on either side would not read on the recitation of claim 22. Although the claim uses the recitation of the term "comprising", this recitation modifies the "set of isolated nucleic acid **molecules**", in that additional nucleic acid molecules can exist in the set, however, the set is limited to 5 nucleic acid molecules consisting of one of the SEQ ID NOS listed (due to recitation of "selected from the group consisting of..."). It is noted that applicants appear to characterize the claim differently, in the response at pages 9-10. Notably, the response appears to argue that the claimed recitation can be limited to a) "at least five of the specifically listed 5

sequences *comprising* 20 nucleotides or their complements" (see page 10, lines 13-16), which specifically conflicts with the interpretation set forth at page 8 of the arguments where it is stated "In the interest of furthering prosecution, Applicants have elected to further restrict pending claim 22 by amending it to require at least 5 nucleic acid molecules selected from a group of **five specific sequences that are each 20 nucleotides in length."** or b) to a single molecule that comprises 5 of the claimed SEQ ID NOS (see for example page 9, lines 5-7). If, however, applicants maintain that the claim is not limited as set forth above by the examiner, but includes the interpretations in the arguments, applicants should indicate which terms in claim 22 are being relied on for such interpretation as well as provide specific support in the specification, including page and line number for the broader interpretation set forth in the arguments. In the interest of compact prosecution, a NEW MATTER REJECTION is set forth below, in the event that applicant's maintain the latter assertions regarding the breadth of claim 22.

4. The rejections made under 35 USC 103(a) are withdrawn in view of the amendments to the claims. The claims now require a combination of at least five isolated nucleic acid molecules where at least 5 of the molecules consist of one of each of the recited SEQ ID NOS or their complements. As noted in the previous office action, SEQ ID NO 1 of Holmes only comprises instant SEQ ID NOS 1, 3, 6 and 9. SEQ ID NOS 2, 4, 5, 7, 8, and 10 are not imbedded in the sequences of Holmes as they all contain mismatches with regard to the sequence of Holmes. There is no teaching or suggestion in Holmes, or the prior art, to construct nucleic acid molecules with the specific sequence of SEQ ID NOS 2, 4, 5, 7, 8, or 10. Since claim 22 now requires 5 of SEQ ID NOS 6-10 or their complements, any combination of 5 from the group recited in claim 22, would yield a set with at least a single molecule which is not taught or suggested by the prior

art. Applicant's arguments at pages 9-10, regarding the teachings of Holmes as well as the attempt at recharacterizing, at page 7, the assertions made in the previous response to restriction requirement are not persuasive; however they are moot in view of the amendment to claim 22.

Claim Rejections - 35 USC § 112

5. Claims 22 and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This includes a NEW MATTER REJECTION, necessitated by assertions made in Applicant's response.

Claim 29 is directed to a set of nucleic acid molecules which comprises at least 5 isolated nucleic acid molecules selected from SEQ ID NOS 6-10 or their complements and additionally to nucleic acids molecules from 10-250 nucleotides long which need be identical to the recited SEQ ID NOS: in as few as 10 contiguous nucleotides and which are to be used in nucleic acid hybridization or amplification to detect all representatives of *Salmonella enterica* subspecies: *enterica*, *salamae*, *arizonae*, *diarizonae*, *houtenai*, *bongori*, and *indica*. The claims encompass a large genus of nucleic acid molecules which includes nucleic acid molecules which minimally only require 10 contiguous nucleotides from one of SEQ ID NOS 1-5 or their complements and function as set forth in claim 22. .

The specification discloses the sequences of SEQ ID NOS 1-10 and teaches that the sequences are identical or altered with respect to a specific region of a fragment of Salmonella typhimurium LT2 chromosome which is taught by Holmes et al in WO9500664 (the fragment is

denoted as SEQ ID NO 1 in WO9500664). The disclosed structural features of SEQ ID NOS 1-10, however, do not represent a substantial portion of the claimed genus. The claimed limitation that the sequences are used to detect all representatives of *Salmonella enterica* subspecies *enterica, salamae, arizonae, diarizonae, houtenae, bongori*, and *indica* is not adequate to describe other relevant identifying characteristics of the claimed genus because the specification has not described any distinguishing characteristics of the undisclosed possible additional sequences which are encompassed by the claims that would allow the detection of all representatives of *Salmonella enterica* subspecies *enterica, salamae, arizonae, diarizonae, houtenae, bongori*, and *indica*. McClelland teaches that S. Bongori and S. Arizonae share 85% and 83% homology with coding sequences of the LT2 chromosome, illustrating that considerable variability exists between the different species. However the specification has not taught or described the identity of sequences which could be used to detect the different Salmonella species recited in the claims, nor has the specification provided an alignment of the chromosomes of the different Salmonella species recited such that the skilled artisan would be able to determine which sequences could be used to detect all representatives of *Salmonella enterica* subspecies recited.

Isolated nucleic acids selected from the group consisting of SEQ ID NOS 1-9 and 10 and complements of such meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to and encompass variants and homologs, none of which meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Additionally, the response appears to assert that claim 22 can be limited to a single molecule that comprises 5 of the claimed SEQ ID NOS (see for example page 9, lines 5-7). The specification has been thoroughly reviewed but does not appear to provide support for this interpretation.

Response to Arguments

6. The response traverses the rejection and asserts that the claims have been amended to refer to nucleic acid molecules comprising specific nucleotide sequences identified by the ten identified sequenced numbers or their complements. This argument has been thoroughly reviewed but was not found persuasive. Claim 29 continues to be drawn to sequences which minimally only require 10 contiguous nucleotides from SEQ ID NOS 1-5 or their complements and the functional recitation that they are used to detect all representatives of *Salmonella enterica* subspecies *enterica, salamae, arizonae, diarizonae, houtenae, bongori*, and *indica.* The specification has not described any distinguishing characteristics of the undisclosed possible additional sequences which are encompassed by the claims that would allow the detection of all representatives of *Salmonella enterica* subspecies *enterica, salamae, arizonae, diarizonae, houtenae, bongori*, and *indica*, nor has the specification taught which portions from within the recited SEQ ID NOS would function as claimed. It appears that a certain combination of specific SEQ ID NOS were used to identify the species set forth in the claims. However, the specification does not teach which portions of the specific SEQ ID NOS are diagnostic for each species, nor how many nucleotides from each SEQ ID NO: are needed to perform as recited in the claims. The specification has not taught or described the identity of additional sequences not included in the SEQ ID NOS, which could be used to detect the different Salmonella species

recited in the claims, nor has the specification provided an alignment of the chromosomes of the different Salmonella species recited such that the skilled artisan would be able to determine which sequences could be used to detect all representatives of *Salmonella enterica* subspecies recited. For these reasons and the reasons made of record above, the rejection is therefore maintained and applied to the newly added claims.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 22 and 29-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,706,472. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are coextensive in scope. The instantly recited claims are drawn to a set of nucleic acid

molecules, comprising 5 isolated nucleic acid molecules which are directed to the sequences of SEQ ID NOS 6-10 and the complements of SEQ ID NO: 6-10 (claim 22) as well as the additional sequences recited in claim 29. The claims of '472 are directed to methods and kits for using one or more of SEQ ID NOS 1-10 and the complements of SEQ ID NOS 1-10 (SEQ ID NOS are identical). Accordingly, the claims are coextensive in scope and not patentably distinct from each other. The rejection is maintained from the previous office action.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-

0752. The examiner can normally be reached Monday, Wednesday and Thursday from 9:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Jehanne Sitton/
Primary Examiner
Art Unit 1634